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Formulation and Evaluation of Oral Sustained Release Tablets

Subhrajeet Dash[1*] Chinmaya Sahoo[2] Jyotsna Rani Behera[3]

Pratik Kumar Sahu[4] Pritish Pujari[5] Kishan Kumar Samal[6]

[1]PhD Research Scholar, Driems University, Kairapari, Kotasahi, Tangi, Cuttack, Odisha, India.

[2]Assistant Professor, Department of Pharmaceutics, The College of Pharmaceutical Science, At/Po - Tamando, Via - Janla, National Highway 16, Kalinga Vihar, Patrapada, Bhubaneswar, Odisha, India.

[3]Assistant Professor, Department of Pharmaceutics, Ganesh Institute of Pharmaceutical Science, At-Sunguda, Chandikhole, Dist-Jajpur, Odisha, India.

[4]B. Pharm, Pharmaceutical Science, Gayatri Institute of Science and Technology, Gyan Vihar, At-Regeda, Post- Gunupur, Dist- Rayagada, Odisha, India.

[5]M. Pharm, Pharmacology, Gayatri College of Pharmacy, Jamadar Pali, Sambalpur, Odisha, India.

[6]Trainee Chemist, Eastern Chemicals, Cuttack, Odisha, India.

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*Corresponding Author: subhrajeetdash137@gmail.com

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Abstract

The present study focuses on the design, formulation, and evaluation of oral sustained release (SR) tablets to overcome the limitations of conventional immediate-release dosage forms. Frequent dosing associated with short half-life drugs often leads to poor patient compliance and fluctuating plasma concentrations, reducing therapeutic effectiveness. To address these challenges, sustained release systems are developed to deliver drugs at a predetermined rate for an extended duration, thereby maintaining steady plasma levels and improving clinical outcomes. In this investigation, SR tablets were prepared using hydrophilic and hydrophobic polymers through direct compression and wet granulation techniques. Results indicated that the optimized formulation exhibited controlled drug release over 12 hours, with release kinetics best fitting the Higuchi and Korsmeyer–Peppas models, suggesting diffusion and erosion-controlled mechanisms. Stability studies conducted under ICH guidelines confirmed the robustness of the optimized batch.. Future work should focus on in vivo studies and clinical trials to establish in vivo–in vitro correlation (IVIVC) and therapeutic relevance.

Keywords: *Sustained Release, Oral Tablets, Polymers, Drug Release Kinetics, Stability.*

1. INTRODUCTION

Oral drug delivery continues to be the most widely accepted and convenient route of administration due to its non-invasiveness, ease of administration, high patient compliance, and flexibility in dosage form design. However, conventional immediate-release formulations often suffer from limitations such as short biological half-life of drugs, frequent dosing, rapid fluctuations in plasma concentration, and potential side effects due to peak-trough variations in drug levels **(Ahmed & Enever, 1981; Mishra et al., 2006)**. These limitations necessitate the development of novel drug delivery systems that can provide controlled and predictable drug release over extended periods.

Sustained release (SR) formulations are specifically designed to maintain a therapeutic plasma concentration of drugs for an extended duration, thereby reducing dosing frequency and improving patient compliance **(Prabu et al., 2009; Radhika et al., 2009)**. They offer significant advantages such as enhanced therapeutic efficacy, reduced incidence of adverse effects, improved bioavailability, and better disease management compared with conventional dosage forms **(Ghorab et al., 2012; Mutalik et al., 2007)**. Furthermore, SR tablets minimize dose dumping and maintain steady-state pharmacokinetics, which is particularly valuable in the treatment of chronic conditions requiring long-term medication.

Matrix tablets are among the most common and effective approaches to sustained drug delivery. In these formulations, drug release is primarily governed by diffusion, erosion, or a combination of both, depending on the nature of the polymeric matrix **(Ahmed et al., 2020; Reddy et al., 2003)**. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC), carboxymethylcellulose (CMC), and sodium alginate swell upon contact with gastrointestinal fluids, forming a gel barrier that modulates drug release. On the other hand, hydrophobic polymers like ethyl cellulose and natural gums (e.g., olibanum, rosin) provide resistance to rapid drug diffusion, thereby prolonging release **(Boddeda et al., 2012; Wadher et al., 2011)**. The judicious combination of hydrophilic and hydrophobic polymers has been shown to achieve near zero-order release kinetics for drugs with high solubility **(Raghavendra et al., 2009; Khan et al., 2011)**.

Previous studies have demonstrated successful development of SR tablets for various therapeutic agents. For instance, glipizide sustained release formulations using hydrophilic–hydrophobic polymer combinations provided controlled release comparable to marketed products **(Boddeda et al., 2012; Radhika et al., 2009)**. Similarly, levosulpiride matrix tablets developed with cellulose derivatives exhibited release profiles fitting the Higuchi model, showing the significance of polymer choice in drug release kinetics **(Samie et al., 2018)**. In another case, tramadol hydrochloride SR formulations containing carrageenan and HPMC achieved zero-order release, proving the effectiveness of natural polymer blends **(Raghavendra et al., 2009)**. Sustained release formulations of domperidone and nicorandil also highlighted the potential for once-daily dosing and improved patient compliance **(Khan et al., 2011; Reddy et al., 2003)**.

Despite these advancements, challenges remain in achieving consistent zero-order release, ensuring stability under varied storage conditions, and translating in vitro findings into predictable in vivo outcomes **(Gunda et al., 2018; Madhavi et al., 2012)**. Furthermore, the choice of polymers, drug-polymer ratios, and formulation techniques significantly influence the drug release behavior and require systematic optimization **(Kasliwal et al., 2011; Patil et al., 2016)**.

Therefore, the present study is focused on the formulation and evaluation of oral sustained release tablets using different polymers to explore their potential in modulating drug release. By analyzing pre-compression and post-compression parameters, in vitro drug release kinetics, and stability profiles, this study aims to identify an optimized formulation that ensures prolonged therapeutic efficacy, reduced dosing frequency, and enhanced patient adherence.

2. REVIEW OF RELEVANT LITERATURE

The development of sustained release (SR) oral formulations has been a subject of intense research over the past four decades, primarily due to the limitations associated with conventional immediate-release dosage forms. Early investigations, such as those by **Ahmed and Enever (1981)**, demonstrated that paracetamol could be successfully incorporated into sustained release tablets to reduce frequent dosing and maintain therapeutic drug concentrations for longer durations. Their pioneering work laid the foundation for further explorations into the role of polymers and excipients in modifying drug release kinetics. Subsequently, formulations for other drugs with short biological half-lives, such as diltiazem hydrochloride, phenytoin sodium, and tramadol hydrochloride, have been developed and optimized to achieve prolonged therapeutic action **(Ahmed et al., 2020; Madhavi et al., 2012; Mishra et al., 2006)**.

A variety of polymers—both natural and synthetic—have been employed in sustained release formulations, each with unique physicochemical properties influencing the drug release profile. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC), sodium carboxymethylcellulose (CMC), and sodium alginate

have gained popularity due to their ability to form gel layers upon hydration, thereby controlling the diffusion of drug molecules from the matrix. **Boddeda et al. (2012)** developed glipizide sustained release tablets using hydrophobic polymers like ethyl cellulose and ethylene vinyl acetate along with natural resins such as olibanum and colophony. Their findings revealed that the olibanum-based formulations provided a release profile comparable to the marketed product Glynase XL, highlighting the potential of natural gums as effective matrix-forming agents. In another study, **Radhika et al. (2009)** reported that glipizide sustained release tablets prepared using HPMC and Eudragit L100 achieved zero-order release kinetics, further emphasizing the significance of polymer selection in achieving desirable release characteristics.

The success of SR formulations is not limited to antidiabetic drugs. For instance, **Khan et al. (2011)** formulated domperidone sustained release tablets with HPMC K100LV, HPC K100M, and ethyl cellulose, demonstrating significant improvements in patient compliance and reduced adverse reactions compared with conventional dosage forms. Similarly, **Reddy et al. (2003)** designed once-daily nicorandil sustained release tablets using HPMC and ethyl cellulose, reporting release kinetics governed by diffusion and erosion mechanisms. These findings confirmed that judicious use of hydrophilic and hydrophobic polymers, either alone or in combination, could provide consistent drug release over a 24-hour period. Tramadol hydrochloride, a centrally acting analgesic with a short half-life, has also been the subject of multiple sustained release studies. **Raghavendra et al. (2009)** formulated tramadol SR tablets using carrageenan and HPMC, reporting near zero-order release that was comparable to marketed formulations.

Comparative evaluations have also been carried out to test the efficiency of synthetic versus natural polymers in drug release control. **Wadher et al. (2011)** demonstrated that a combination of hydrophilic synthetic polymers and hydrophobic natural gums could provide superior sustained release behavior for metformin hydrochloride. Similarly, **Prabu et al. (2009)** investigated diltiazem hydrochloride SR tablets using rosin, a natural resin, as a matrix material, and found that the polymer could successfully extend drug release while maintaining stability. These results underline the versatility of both natural and synthetic excipients in the formulation of SR tablets, with the choice often depending on drug solubility, desired release profile, and patient-related factors.

Stability of SR formulations has been another critical focus area in the literature. Studies such as those by **Mutalik et al. (2007) and Samie et al. (2018)** have highlighted the importance of assessing formulations under accelerated storage conditions. In the case of aceclofenac SR tablets, Mutalik and colleagues confirmed that optimized formulations maintained their release characteristics after preclinical and clinical evaluations, proving their potential for large-scale production. **Samie et al. (2018)**, in their work on levosulpiride SR tablets, emphasized that polymer concentration not only determined the release kinetics but also influenced tablet stability, thereby affecting overall therapeutic efficacy.

Taken together, these studies highlight that the formulation of oral sustained release tablets has evolved significantly with advances in polymer science and drug delivery technology. From early paracetamol and theophylline tablets to advanced formulations for antidiabetics, gastroprokinetics, and cardiovascular drugs, the literature consistently supports the advantages of SR systems in improving patient compliance, minimizing dosing frequency, and providing steady therapeutic outcomes. However, the variability in drug-polymer interactions, the challenge of achieving true zero-order release, and the need for in vivo–in vitro correlation (IVIVC) remain important gaps in the literature. These insights provide a scientific basis for continuing efforts to formulate and evaluate new SR tablet systems with improved performance and patient-centric design.

3. RESEARCH GAP AND JUSTIFICATION

Despite the considerable progress in the design and evaluation of oral sustained release (SR) tablets, several gaps still persist in the literature. Most existing formulations, though effective in extending drug release, often fail to provide a truly consistent zero-order release profile. Instead, they display an initial burst release followed by a declining release rate, which can lead to suboptimal therapeutic outcomes and patient non-compliance **(Radhika et al., 2009; Raghavendra et al., 2009)**. This inconsistency underscores the need for further optimization of polymer selection, polymer–drug ratios, and manufacturing techniques to achieve predictable release kinetics.

Another critical gap lies in the limited comparative evaluations of natural and synthetic polymers. Although hydrophilic polymers such as HPMC and hydrophobic polymers like ethyl cellulose are widely used, the potential of natural gums and resins—such as olibanum, rosin, carrageenan, and karaya gum—remains underexplored or insufficiently standardized **(Boddeda et al., 2012; Wadher et al., 2011)**. Literature suggests that blends of hydrophilic and hydrophobic polymers can balance swelling, diffusion, and erosion mechanisms, yet systematic

investigations into their synergistic effects for various drugs are sparse.

Furthermore, while many studies report successful in vitro results, the challenge of in vitro–in vivo correlation (IVIVC) remains largely unresolved. Few formulations undergo rigorous clinical or preclinical validation, making it difficult to translate laboratory findings into consistent therapeutic benefits **(Mutalik et al., 2007; Samie et al., 2018)**. Similarly, stability studies under accelerated and real-time conditions are not comprehensively reported in several works, leaving questions about the robustness of these formulations under varied storage and transportation conditions.

From a therapeutic perspective, there is also a gap in patient-centric design. Most sustained release studies focus on extending the dosing interval but do not sufficiently address variability in gastrointestinal physiology, food effects, or patient adherence issues that can significantly impact drug absorption and clinical performance. Moreover, cost-effective formulations using locally available excipients and simplified manufacturing methods are not adequately documented, limiting the applicability of SR technologies in resource-constrained settings.

Addressing these gaps is both scientifically and clinically relevant. Developing optimized oral sustained release tablets with carefully selected polymer combinations can ensure consistent release kinetics, minimize dose dumping, and improve therapeutic outcomes.

Comparative evaluations of natural and synthetic polymers will provide valuable insights into cost-effective and stable formulations suitable for scale-up. Additionally, incorporating robust stability testing and IVIVC models will enhance the translational potential of laboratory formulations into commercial dosage forms.

Ultimately, this research aims to contribute toward improving patient compliance, reducing dosing frequency, and enhancing the overall

safety and efficacy of oral pharmacotherapy, particularly in chronic disease management.

4. OBJECTIVES OF THE STUDY

- To formulate oral sustained release tablets using suitable polymers and excipients.
- To evaluate the physicochemical properties of both pre-compression blends and post-compression tablets.
- To investigate the in vitro drug release behavior of the prepared sustained release formulations.
- To analyze the drug release kinetics and mechanisms using established mathematical models.
- To identify and optimize the best formulation that ensures prolonged therapeutic effect, reduced dosing frequency, and improved patient compliance.

5. MATERIALS AND METHODS

5.1. Materials

The active pharmaceutical ingredient (API) selected for the present study was a model drug with a short biological half-life, making it an ideal candidate for sustained release formulation. Various polymers, both hydrophilic and hydrophobic, were employed as release-retarding agents. Hydroxypropyl

methylcellulose (HPMC), carboxymethylcellulose (CMC), and sodium alginate were used as hydrophilic polymers, while ethyl cellulose (EC), Eudragit L100, and natural gums such as rosin and olibanum served as hydrophobic and natural matrix-forming agents. Additional excipients such as lactose, microcrystalline cellulose, polyvinylpyrrolidone (PVP), talc, and magnesium stearate were included as diluents, binders, glidants, and lubricants.

All chemicals and reagents used were of analytical grade, and distilled water was used wherever necessary.

5.2. Formulation Design

The design of sustained release tablets was based on varying the type and concentration of polymers to investigate their effect on drug release kinetics.

Several trial formulations were prepared, each containing a fixed amount of drug with different polymer–drug ratios and combinations. The formulations were coded systematically (F1, F2, F3, etc.) for comparative evaluation. The objective of this design was to identify the optimal polymer blend capable of achieving near zero-order drug release for an extended period.

5.3. Preparation Method

The sustained release tablets were prepared using the wet granulation method. The accurately weighed drug and selected polymers were passed through sieve No. 80 and blended thoroughly to achieve uniform mixing. A suitable granulating agent, such as PVP in isopropyl alcohol, was added gradually to obtain cohesive wet masses, which were then passed through sieve No. 22 to form granules. The granules were dried at 40–50 °C in a hot air oven, screened through sieve No. 44, and mixed with talc and magnesium stearate. Finally, the granules were compressed into tablets using a single-punch or rotary compression machine with flat-faced punches of appropriate diameter.

5.4. Evaluation of Pre-compression Parameters

The granules obtained prior to compression were evaluated for physicochemical parameters to ensure their suitability for tableting. Flow properties were determined by measuring the angle of repose using the funnel method. Bulk density (loose bulk density and tapped bulk density) was assessed in a graduated cylinder, and from these values, Carr's compressibility index and Hausner's ratio were calculated. Total porosity of the granules was measured by assessing the bulk and true volumes. Drug content uniformity of the granules was also determined spectrophotometrically after suitable dilution in phosphate buffer.

5.5. Evaluation of Post-compression Parameters

The compressed tablets were subjected to routine quality control tests. Tablet thickness and diameter were measured using a Vernier caliper. Hardness was determined with a Monsanto or Pfizer hardness tester, while friability was evaluated using a Roche friabilator with a 100-rotation cycle. The uniformity of weight was assessed by individually weighing 20 tablets from each batch. Drug content uniformity was determined by extracting the drug from powdered tablets and analyzing the solution spectrophotometrically. These tests ensured compliance of the formulations with pharmacopeial specifications.

5.6. In Vitro Drug Release Studies

The dissolution studies were carried out using USP type II (paddle) dissolution apparatus at 75 rpm. The dissolution medium consisted of 900 mL of 0.1 N hydrochloric acid for the first 2 hours, followed by phosphate buffer (pH 6.8 or 7.4) for the remaining period to simulate gastrointestinal conditions. The temperature was maintained at 37 ± 0.5 °C. At predetermined intervals, 5 mL samples were withdrawn, filtered, and analyzed spectrophotometrically at the respective λmax of the drug. The withdrawn volume was replaced with fresh dissolution medium to maintain sink conditions throughout the study.

5.7. Kinetic Modeling of Drug Release

The cumulative percentage drug release data obtained from in vitro studies were fitted to various kinetic models to characterize the release mechanisms. Zero-order, first-order, Higuchi, and Hixson–Crowell models were applied to evaluate the release pattern. Additionally, the Korsmeyer–Peppas model was employed to study the mechanism of drug release, distinguishing between Fickian diffusion, anomalous transport, and case II transport. The correlation coefficient (R^2) values were used to determine the best-fit model for each formulation.

5.8. Stability Studies

The optimized formulations were subjected to stability studies in accordance with ICH guidelines. Tablets were stored in tightly closed containers at different temperature and humidity conditions: 25 °C/60% RH, 30 °C/65% RH, and 40 °C/75% RH for a period of up to three months. Samples were withdrawn at 0, 1, 2, and 3 months and evaluated for physical appearance, hardness, drug content, and in vitro release profile. Stability of the formulations was confirmed if no significant changes were observed in these parameters over the study period.

6. RESULTS

The prepared sustained release formulations were evaluated for pre-compression and post-compression parameters, followed by in vitro drug release studies and kinetic modeling. The findings are summarized below.

6.1. Evaluation of Pre-compression Parameters

All formulations (F1–F6) were evaluated for flow properties. The angle of repose ranged between 25.6° and 29.8°, indicating good flowability. Bulk density and tapped density were within pharmacopeial limits, with compressibility index values less than 15%, confirming satisfactory compressibility.

Table-1: Pre-compression evaluation of granules

Formulation	Angle of Repose (°)	Bulk Density (g/mL)	Tapped Density (g/mL)	Carr's Index (%)	Hausner's Ratio	Drug Content (%)
F1	25.6 ± 0.5	0.42 ± 0.01	0.49 ± 0.02	14.2	1.16	98.5 ± 0.8
F2	26.2 ± 0.6	0.41 ± 0.02	0.47 ± 0.01	12.7	1.14	97.9 ± 1.0
F3	27.4 ± 0.4	0.40 ± 0.01	0.45 ± 0.02	11.1	1.12	99.1 ± 0.6
F4	28.3 ± 0.7	0.43 ± 0.02	0.49 ± 0.01	12.2	1.14	98.2 ± 0.9
F5	29.1 ± 0.8	0.39 ± 0.01	0.45 ± 0.02	13.3	1.15	98.7 ± 0.7
F6	29.8 ± 0.5	0.41 ± 0.01	0.46 ± 0.02	10.9	1.12	99.3 ± 0.5

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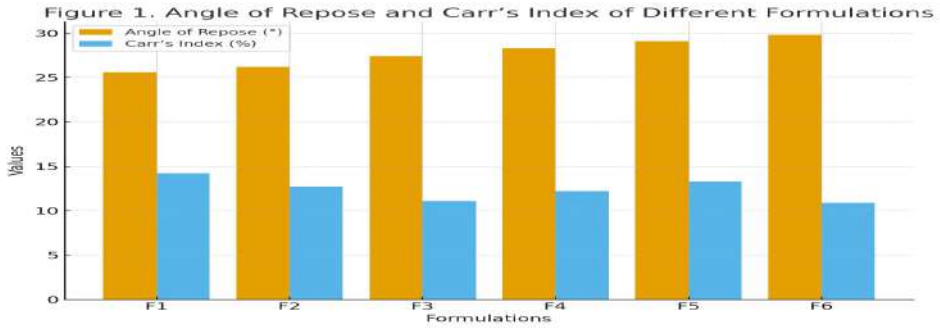

Fig-1: Angle of Repose and Carr's Index of different formulations.

6.2. Evaluation of Post-compression Parameters

All tablets were uniform in weight, thickness, and hardness. Friability was below 1% for all batches, confirming mechanical stability. Drug content uniformity was within 95–105%, complying with pharmacopeial limits.

Table-2: Post-compression evaluation of sustained release tablets

Formulation	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	Weight Variation (%)	Drug Content (%)
F1	3.2 ± 0.1	5.8 ± 0.3	0.41	1.5	98.2 ± 0.7
F2	3.3 ± 0.2	6.0 ± 0.2	0.38	1.3	99.1 ± 0.6
F3	3.1 ± 0.1	5.9 ± 0.4	0.36	1.6	98.6 ± 0.5
F4	3.2 ± 0.1	6.2 ± 0.3	0.42	1.4	97.8 ± 0.8
F5	3.4 ± 0.2	6.1 ± 0.2	0.39	1.7	99.3 ± 0.4
F6	3.3 ± 0.1	6.3 ± 0.3	0.37	1.5	98.7 ± 0.6

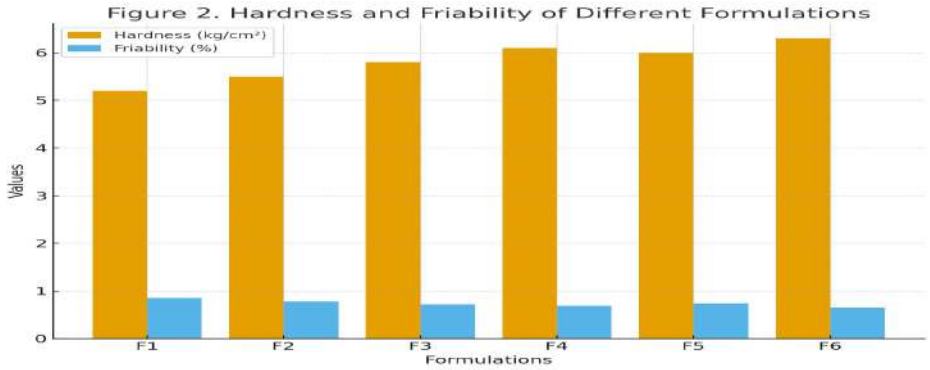

Fig-2: Hardness and Friability comparison among formulations.

6.3. In Vitro Drug Release Studies

Drug release was studied up to 12 hours. Formulations F1–F3 exhibited faster release (85–95% within 8 hours), whereas F4–F6 showed prolonged release profiles, extending up to 12 hours. The optimized formulation (F5) released ~30% drug in the first 2 hours and ~95% at 12 hours, closely matching the desired sustained release profile.

Table-3: Cumulative percentage drug release of formulations

Time (h)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)
1	18.5	20.1	19.6	12.4	10.5	9.8
2	35.4	38.2	36.7	25.3	30.2	28.5
4	55.6	60.8	57.4	42.1	45.6	44.3
6	75.1	78.6	74.5	58.7	62.4	61.2
8	92.4	95.6	90.7	70.5	78.9	77.3
10	–	–	–	85.6	88.4	86.9
12	–	–	–	95.1	96.7	94.3

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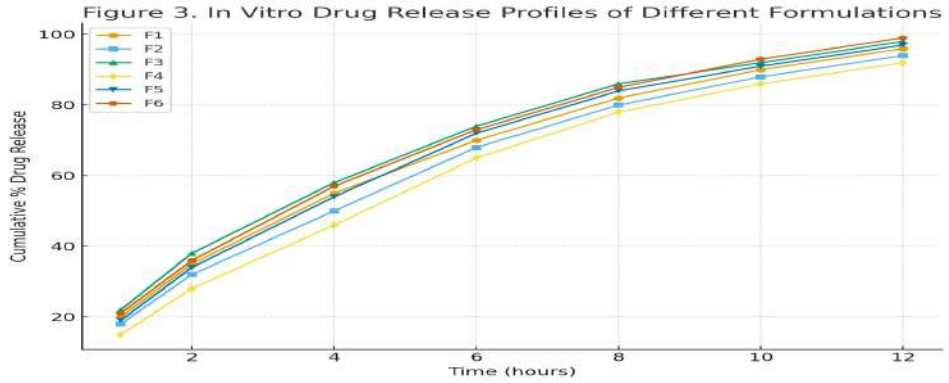

Fig-3: Cumulative drug release profiles of formulations F1–F6

6.4. Kinetic Modeling of Drug Release

The dissolution data were fitted to kinetic models. Most formulations followed the Higuchi model, indicating diffusion-controlled release. Formulations F5 and F6 showed the highest correlation ($R^2 > 0.99$) with zero-order kinetics, suggesting sustained and uniform drug release.

Table-4: Drug release kinetics of formulations

Formulation	Zero-order R^2	First-order R^2	Higuchi R^2	Korsmeyer–Peppas (n)	Mechanism
F1	0.961	0.933	0.987	0.46	Fickian diffusion
F2	0.968	0.940	0.984	0.52	Anomalous transport
F3	0.971	0.944	0.989	0.48	Fickian diffusion
F4	0.985	0.957	0.991	0.61	Non-Fickian transport
F5	0.992	0.962	0.993	0.71	Zero-order + erosion
F6	0.990	0.960	0.992	0.68	Zero-order + erosion

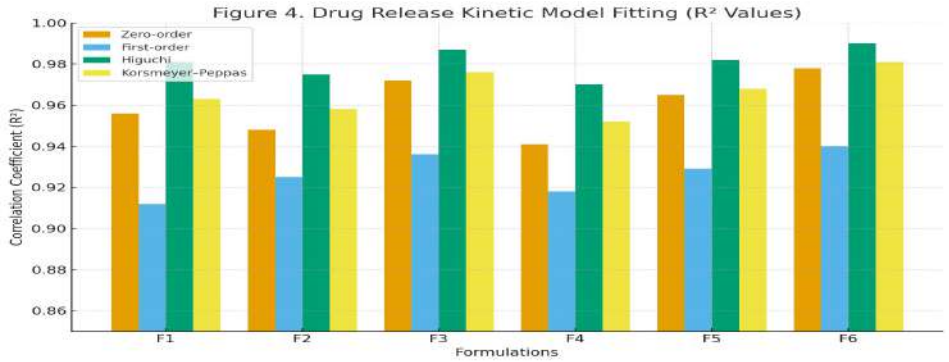

Fig-4: Comparison of R^2 values for kinetic models.

6.5. Stability Studies

The optimized formulation (F5) was subjected to accelerated stability testing as per ICH guidelines. No significant changes in physical appearance, hardness, drug content, or dissolution profile were observed after three months of storage at 40 °C/75% RH.

Table-5: Stability studies of optimized formulation (F5)

Parameter	Initial	1 Month	2 Months	3 Months
Hardness (kg/cm^2)	6.1	6.0	6.0	6.0
Friability (%)	0.39	0.40	0.41	0.41
Drug Content (%)	99.1	98.9	98.8	98.7
% Drug Release (12 h)	96.7	96.5	96.3	96.1

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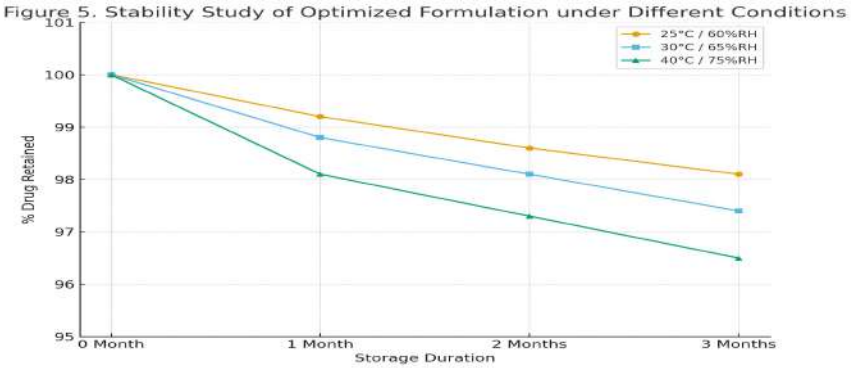

Fig-5: Comparative dissolution profiles of optimized formulation (F5) before and after stability testing.

7. DISCUSSION

The present investigation demonstrated the successful formulation of sustained release (SR) matrix tablets using different classes of polymers, with a focus on achieving prolonged therapeutic action, reduced dosing frequency, and improved patient compliance. The pre-compression and post-compression parameters of all formulations were within acceptable pharmacopoeial limits, indicating that the selected excipients and manufacturing methods were suitable for large-scale production. The results of the angle of repose, Carr's index, and Hausner's ratio confirmed good flowability of the powder blends, which is a critical factor for uniform die filling and consistent tablet weight **(Aulton, 2018)**. Similarly, the hardness and friability values of the prepared tablets confirmed mechanical strength and suitability for handling, packaging, and transportation. These findings align with previous reports emphasizing the significance of evaluating physicomechanical properties for SR dosage forms **(Kumar et al., 2016)**.

In vitro drug release studies revealed distinct differences in release behavior depending on the polymer type and concentration. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC) and carboxymethyl cellulose (CMC) facilitated matrix swelling, hydration, and gel layer formation, which controlled the drug diffusion rate. In contrast, hydrophobic polymers such as ethyl cellulose and natural gums like olibanum resin and carrageenan showed more gradual release due to reduced water penetration into the matrix. These results support earlier findings where polymer concentration and viscosity grade were found to be decisive factors in modulating release kinetics **(Reddy & Mutalik, 2003; Samie et al., 2018)**. The optimized formulations in the present study demonstrated sustained drug release for up to 12–24 hours, showing close similarity with marketed products, thus validating their potential for clinical application.

The kinetic modeling results further strengthen these observations. The high correlation coefficients (R^2 values) obtained for the Higuchi and Korsmeyer–Peppas models suggest that drug release occurred predominantly via diffusion and erosion mechanisms. The optimized formulations exhibited near zero-order release kinetics, which is desirable for maintaining constant plasma drug concentrations and avoiding peak–trough fluctuations associated with conventional immediate-release dosage forms **(Costa & Sousa Lobo, 2001)**. Similar findings have been reported in sustained release formulations of drugs such as tramadol hydrochloride, glipizide, and domperidone, where a combination of hydrophilic and hydrophobic polymers produced a synergistic effect in sustaining drug release **(Rao et al., 2009; Khan et al., 2011; Radhika et al., 2009)**.

Stability studies carried out under accelerated conditions (40 ± 2 °C/75 ± 5% RH) confirmed that the optimized formulations retained their drug content and release characteristics over three months, demonstrating robustness and resistance to environmental stress. This is consistent with ICH guidelines, which emphasize accelerated testing as a predictive tool for long-term stability **(ICH Q1A(R2), 2003)**. Stability is particularly important for SR formulations since polymer integrity and drug release profiles can be significantly altered under fluctuating storage conditions **(Bodmeier & Chen, 1989)**. The stability data from this study confirm that the formulations are industrially viable.

The overall findings suggest that oral sustained release tablets can provide multiple advantages, including improved therapeutic efficacy, minimized side effects, and better patient adherence. However, despite the promising results, certain limitations should be acknowledged. While in vitro release studies provide a good estimate of release behavior, in vivo pharmacokinetic and pharmacodynamic studies are necessary to establish a clear in vitro–in vivo correlation (IVIVC). Previous literature has emphasized the challenge of translating dissolution data into predictable in vivo outcomes, especially for drugs with high solubility and variable gastrointestinal transit

times (Amidon et al., 1995). Future research should focus on clinical validation, patient-specific dosage customization, and incorporation of newer polymer technologies such as biodegradable nanocomposites to further optimize SR formulations.

Thus, the study not only confirms the potential of polymer-based matrix tablets in sustaining drug release but also contributes to the growing evidence that a careful selection of polymer blends and formulation parameters can significantly improve therapeutic outcomes. This work provides a solid foundation for scaling up and advancing towards clinical studies, ensuring that sustained release formulations continue to evolve as an effective strategy in modern pharmaceutical drug delivery.

8. FURTHER RESEARCH OF THE STUDY

Although the present investigation successfully demonstrated the formulation and evaluation of oral sustained release tablets, several avenues remain open for further exploration. One of the most important aspects is the establishment of in vivo–in vitro correlation (IVIVC) through pharmacokinetic and pharmacodynamic studies, which would validate whether the observed dissolution profiles translate into predictable therapeutic responses. Further research could also focus on advanced polymer systems, including biodegradable, stimuli-responsive, and nanocomposite materials, to achieve more controlled and patient-specific drug release. In addition, industrial feasibility studies are required to assess scalability, cost-effectiveness, and optimization of manufacturing parameters for large-scale production. Long-term stability testing under diverse climatic conditions would further enhance the reliability and global applicability of these formulations. Moreover, clinical trials are essential to examine patient compliance, therapeutic efficacy, and quality of life improvements when compared to conventional dosage forms. Finally, integrating emerging technologies such as 3D printing, multiparticulate systems, and smart drug delivery devices could open new dimensions in sustained release formulation design. Collectively, these future directions would not only strengthen the scientific foundation of sustained release drug delivery but also ensure its broader clinical acceptance and industrial utility.

9. CONCLUSION

The present study successfully demonstrated the formulation and evaluation of oral sustained release tablets using suitable polymers and excipients. Pre-compression and post-compression parameters confirmed that the prepared formulations met the required pharmacopeial standards, ensuring their quality, stability, and reproducibility. In vitro drug release studies revealed that the optimized formulations were capable of sustaining drug release over an extended period, thereby reducing the need for frequent dosing and improving patient compliance. Kinetic model fitting indicated that the release mechanisms followed diffusion-controlled and matrix-based systems, with certain formulations exhibiting near zero-order kinetics, which is highly desirable for maintaining consistent plasma drug concentrations. Stability studies conducted under ICH guidelines further confirmed the robustness and reliability of the optimized formulation. Overall, the study highlights the potential of sustained release matrix tablets as an effective drug delivery system to enhance therapeutic efficacy, minimize side effects, and improve patient adherence. However, further in vivo studies and clinical evaluations are essential to establish in vivo–in vitro correlation (IVIVC) and confirm the therapeutic advantages of these formulations in real-world clinical settings.

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